4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 822

[Docket No. FDA-2021-N-0246]

Medical Devices; Technical Amendments

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is amending its medical device regulations to update mailing address information and to reduce (from three to one) the number of copies of certain documents that need to be submitted to FDA. The rule does not impose any new regulatory requirements on affected parties. This action is editorial in nature and is intended to improve the accuracy of the Agency's regulations, and to remove a submission requirement that is no longer necessary.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: Madhusoodana Nambiar, Office of Policy, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, Rm. 5519, Silver Spring, MD 20993-0002, 301-796-5837.

SUPPLEMENTARY INFORMATION:

I. Background

The FDA Center for Devices and Radiological Health (CDRH) has reorganized to create an agile infrastructure that can adapt to future organizational, regulatory, and scientific needs (84 FR 22854, May 20, 2019; 85 FR 18439, April 2, 2020). The newly formed Office of Product Evaluation and Quality (OPEQ) combined the former Office of Compliance, the Office of Device Evaluation, the Office of Surveillance and Biometrics, and the Office of In Vitro

Diagnostics and Radiological Health, with a focus on a Total Product Lifecycle (TPLC) approach to medical device oversight. Within OPEQ there are Offices of Health Technology that focus on the TPLC review of specific types of medical devices as well as cross-cutting offices focusing on specific policy and programmatic needs including the Office of Regulatory Programs and the Office of Clinical Evidence and Analysis. As part of this technical amendment, we are making a change to correctly identify the address for obtaining particular information. We are also amending the requirement for the submission of multiple copies of certain documents to a single copy, as FDA's receipt of multiple copies is no longer necessary. The changes published in this notice are non-substantive and editorial in nature.

II. Description of the Technical Amendments

One regulation specified in this notice is being revised to make a non-substantive editorial change to update particular mailing address information. For the other two regulations specified in this notice, we are removing the requirements for submission of multiple copies of certain postmarket surveillance-related documents, to instead require submission of only one copy, because the requirement for multiple copies is no longer necessary. The rule does not impose any new regulatory requirements on affected parties. The amendments are editorial in nature and should not be construed as modifying any substantive standards or requirements.

III. Notice and Public Comment

Publication of this document constitutes final action under the Administrative Procedure Act (APA). The APA generally exempts "rules of agency organization, procedure, or practice" from the requirements of notice and comment rulemaking. (5 U.S.C. 553(b)(A)). Rules are also generally exempt from such requirements when an Agency "for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest" (5 U.S.C. 553(b)(B)).

FDA has determined that this rulemaking meets the APA's notice and comment exemption requirements. All the revisions FDA publishes through this notice make technical or non-substantive changes. Some of these revisions pertain solely to the CDRH reorganization, and constitute "rules of agency organization, procedure, or practice" not subject to the requirements of notice and comment under 5 U.S.C. 553(b)(A). The balance of these revisions reduces (from three to one) the number of copies of certain documents that need to be submitted to FDA. Such technical, non-substantive change is "a routine determination, insignificant in nature and impact, and inconsequential to the industry and to the public." (*Mack Trucks, Inc.* v. *EPA*, 682 F.3d 87, 94 (D.C. Cir. 2012)) (quotation marks and citation omitted). FDA accordingly for good cause finds that notice and public procedure thereon are unnecessary for this reduction in the number of copies of certain documents that must be submitted.

The APA allows an effective date less than 30 days after publication as "provided by the agency for good cause found and published with the rule" (5 U.S.C. 553(d)(3)). An effective date 30 or more days from the date of publication is unnecessary in this case because the amendments do not impose any new regulatory requirements on affected parties, and affected parties do not need time to "adjust to the new regulation" before the rule takes effect (*Am. Federation of Government Emp., AFL-CIO* v. *Block*, 655 F.2d 1153, 1156 (D.C. Cir. 1981)). Therefore, FDA finds good cause for the amendments to become effective on the date of publication of this action.

List of Subjects in 21 CFR Part 822

Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under the authority delegated to the Commissioner of Food and Drugs, 21 CFR part 822 is amended as follows:

PART 822--POSTMARKET SURVEILLANCE

1. The authority citation for part 822 continues to read as follows:

Authority: 21 U.S.C. 331, 352, 360i, 360l, 371, 374.

2. Revise § 822.8 to read as follows:

§ 822.8 When, where, and how must I submit my postmarket surveillance plan?

You must submit your plan to conduct postmarket surveillance within 30 days of the date you receive the postmarket surveillance order. For devices regulated by the Center for Biologics Evaluation and Research, send your submission to the Food and Drug Administration, Center for Biologics Evaluation and Research, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G112, Silver Spring, MD 20993-0002. For devices regulated by the Center for Drug Evaluation and Research, send your submission to the Central Document Room, Center for Drug Evaluation and Research, Food and Drug Administration, 5901-B, Ammendale Rd., Beltsville, MD 20705-1266. For devices regulated by the Center for Devices and Radiological Health, send your submission to the Document Mail Center, 10903 New Hampshire Ave., Bldg. 66, Rm. G609, Silver Spring, MD 20993-0002. When we receive your original submission, we will send you an acknowledgment letter identifying the unique document number assigned to your submission. You must use this number in any correspondence related to this submission.

3. Amend § 822.12 by revising the first sentence to read as follows:

§ 822.12 Do you have any information that will help me prepare my submission or design my postmarket surveillance plan?

Guidance documents that discuss our current thinking on preparing a postmarket surveillance submission and designing a postmarket surveillance plan are available on the Center for Devices and Radiological Health's website, the Food and Drug Administration main website, and from the Food and Drug Administration, Center for Devices and Radiological Health, Office of Policy, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993-0002. * * *

4. Revise § 822.21 to read as follows:

§ 822.21 What must I do if I want to make changes to my postmarket surveillance plan after you have approved it?

You must receive our approval in writing before making changes in your plan that will affect the nature or validity of the data collected in accordance with the plan. To obtain our approval, you must submit the request to make the proposed change and revised postmarket surveillance plan to the applicable address listed in § 822.8. You may reference information already submitted in accordance with § 822.14. In your cover letter, you must identify your submission as a supplement and cite the unique document number that we assigned in our acknowledgment letter for your original submission, specifically identify the changes to the plan, and identify the reasons and justification for making the changes. You must report changes in your plan that will not affect the nature or validity of the data collected in accordance with the plan in the next interim report required by your approval order.

Dated: March 11, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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